



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
San Francisco District Office
1431 Harbor Bay Parkway
Alameda, CA 94502

Telephone: (510) 337-6820
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Edward C. Yu
VP of Clinical Research & Regulatory Affairs
Conceptus Inc.
331 East Evelyn Avenue
Mountain View, CA. 94041

Dear Mr. Yu:

We have received your letter of 01/20/2011, responding to a List of Inspectional Observations, FDA Form 483, issued on January 6th, 2011, at the conclusion of an inspection of your facility located in Mountain View, CA.

We find that the corrective actions which you propose, once they are fully implemented, should adequately address the observations.

Neither this letter nor the FDA 483 is intended to indicate that the Food and Drug Administration will or will not take any particular regulatory or administrative action with regard to our findings. You are reminded that it is the responsibility of your firm's management to assure compliance with the provisions of the Food, Drug, and Cosmetic Act.

Should you have any further questions or comments regarding this matter, please feel free to contact me at the district office address provided above in the letterhead.

Sincerely,

Luis Solórzano

Director, Investigations Branch